

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

No. 7:22-cv-00073-M

CENTER FOR ENVIRONMENTAL
HEALTH, *et al.*,

Plaintiffs,

v.

MICHAEL REGAN, in his official
capacity as Administrator of the U.S.
Environmental Protection Agency, *et al.*,

Defendants.

**SUPPLEMENTAL BRIEFING IN
SUPPORT OF DEFENDANTS'
MOTION TO DISMISS**

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In accordance with the Court's January 23, 2023 order, ECF No. 71, Defendant EPA responds to the three questions posed by the Court as follows:

1. **Plaintiffs seek judicial review of EPA's decision to grant a single "petition" for an order compelling health and environmental effects testing regarding PFAS.**

TSCA section 21 authorizes "citizens petitions" "for the issuance, amendment, or repeal of a rule" under TSCA sections 4, 6, or 8, or "an order" under TSCA section 4, 5(e), or 5(f). Id. § 2620(a). The petition must set forth the facts which the petitioner claims establish the necessity of the rule or order requested.

While TSCA does not define the term "petition," here, Plaintiffs and EPA agree that there is a single petition in which Plaintiffs requested that EPA "issue a test rule or order requiring Chemours to fund studies necessary to understand the likely health and environmental risks from past and ongoing exposure to the 54 PFAS." Pet. 2, ECF No. 49-1. Plaintiffs' petition also broadly characterizes the risk associated with the 54 identified substances (as opposed to making any claim that each substance has a risk distinct from one another), generally asserting that PFAS "as a class" may present an unreasonable risk to health and the environment. Pet. 16-18. Although EPA initially denied the petition in a single action that it published in the Federal Register, 86 Fed. Reg. 6,602 (Jan. 22, 2021), upon reconsideration, EPA decided "to grant the petition . . . to issue a rule or order under TSCA section 4(a)(1)(A)(i) compelling health and environmental effects testing regarding PFAS." Dec. 2021 Resp. 2, ECF No. 49-2. And at the January 20, 2023 status conference, Plaintiffs acknowledged that they consider there to be one "petition." This acknowledgment is consistent with Plaintiffs' written characterization of the

petition as a single petition. *See, e.g.*, Pet. 1, ECF No. 49-1; Am. Compl. ¶ 3, ECF No. 32 (referencing the petition in the singular). EPA agrees that there is one petition seeking an order compelling testing.

Even if there were a dispute as to whether there is a single petition, the Court should defer to EPA's reasonable treatment of the petition as a single petition. *Center for Biological Diversity v. Jackson*, 815 F. Supp. 2d 85 (D.D.C. 2011), is instructive. There, the plaintiffs submitted a single document requesting that EPA regulate (1) lead shot and bullets and (2) lead fishing sinkers. *Id.* at 87. EPA treated the separate requests in the document as independent petitions. EPA denied the first request regarding lead shot and bullets and later, and for different reasons, denied the second request regarding lead fishing sinkers. EPA published its reasons for each denial separately in the Federal Register. The plaintiffs challenged EPA's decisions, and EPA moved to dismiss in part regarding the request to regulate lead shot and bullets because the complaint was filed outside of the sixty-day deadline under TSCA. The plaintiffs argued that their submission constituted a single petition and that it was improper for EPA to treat it as two separate petitions.

The court deferred to EPA's determination that the requests should be addressed separately based on the different legal and factual considerations applicable to each issue. *Id.* at 93 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). The court further held that "EPA has expertise in handling TSCA petitions"

and that the court “should defer to the Agency’s determination of the most efficient way to address rulemaking documents containing multiple requests.” *Id.* at 94.

Here, EPA’s treatment of the petition as a single petition to issue a TSCA section 4 rule or order compelling health and environmental effects testing regarding PFAS is reasonable. EPA provided a reasoned explanation, informed by its expertise and experience administering TSCA, for its use of categories and tiered testing and for how EPA’s PFAS National Testing Strategy (“Testing Strategy”) addresses the 54 substances identified in the petition. *See* Mem. in Supp. of EPA’s Mot. to Dismiss 6–10, ECF No. 49; Dec. 2021 Resp. 9–22.

2. EPA’s proceeding upon granting Plaintiffs’ petition comports with statutory requirements that favor a category-based approach to test orders.

TSCA mandates that EPA “reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this subchapter, the use of vertebrate animals in the testing of chemical substances.” 15 U.S.C. § 2603(h)(1). To advance this mandate, TSCA expressly directs EPA to group similar chemical substances into categories in which the testing of a single representative substance would provide useful information for other chemical substances in the same group. *Id.* § 2603(h)(1)(B)(ii) (EPA shall reduce “the use of vertebrate animals in the testing of chemical substances or mixtures” by, *inter alia*, encouraging “the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category . . .”); *see also id.* § 2625(c)(1). And under the 2020 National Defense Authorization Act, EPA is required

to develop a process for prioritizing PFAS that should be subject to additional research efforts that is based on the substance's or "class[] of substances' " potential effects. *Id.* § 8962(a)(2).

In granting Plaintiffs' petition, EPA anticipates addressing the 54 substances identified in Plaintiffs' petition in a manner that embraces this statutory preference for a "category-based" approach to issuing test orders. In accordance with its Testing Strategy,¹ EPA has begun issuing test orders on substances that serve as representatives for categories of PFAS. EPA Dec. 2021 Resp. 2-3.² As explained in EPA's Motion to Dismiss, the results of the test orders for representative samples will inform a majority of the 54 substances identified in Plaintiffs' petition. Mem. in Supp.

¹ See also U.S. Environmental Protection Agency, NATIONAL PFAS TESTING STRATEGY: IDENTIFICATION OF CANDIDATE PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS) FOR TESTING (October 2021). Available at <https://www.epa.gov/system/files/documents/2021-10/pfas-natl-test-strategy.pdf> (last accessed June 7, 2022).

² On June 6, 2022, EPA issued the first of the expected 24 PFAS testing orders, directing, among others, Chemours to develop and submit information regarding 6:2 fluorotelomer sulfonamide betaine (CASRN 34455-29-3). See EPA 6:2 fluorotelomer sulfonamide betaine testing order (available at <https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0897>) (last accessed June 17, 2022).

On January 4, 2023, EPA issued another TSCA section 4 order directing several corporations, including the Chemours Company, to conduct a series of health effect and toxicity studies regarding the PFAS Hexafluoropropylene oxide ("HFPO"). ECF No. 65-1. HFPO is one of the 54 substances identified by Plaintiffs in their petition. See Dkt. No. 49-1 at 16. As one of the initial test orders issued for the representative PFAS identified in the Testing Strategy, it is expected that the results from these studies will shed information for other PFAS in the same category as HFPO.

of EPA's Mot. to Dismiss 8-9. And as explained in EPA's motion to dismiss and in its December 2021 response, EPA's Testing Strategy is an iterative process that is both dynamic and evolving. *Id.* at 9; EPA Dec. 2021 Resp. 3, 15-16; *see also id.* at 10 (describing the Testing Strategy as a "dynamic and evolving approach" to understanding PFAS, listing non-exhaustive examples of how the Agency would anticipate modifying the Testing Strategy). Thus, as EPA collects and reviews additional data, it may expand the scope of the Testing Strategy, refine the PFAS categories used and/or adjust its analysis of the usefulness and scientific validity of the obtained information as representative of other substance. EPA Dec. 2021 Resp. 3, 15-16.

EPA's anticipated proceeding in response to granting Plaintiffs' petition, in other words, comports with statutory requirements that express a preference for a "category-based" approach where similar substances are grouped and test orders are issued for a single representative substance that would shed information on substances in the same category. Plaintiffs' proposals—without regard for this approach—ultimately circumvents the statutory provisions that inform how TSCA test orders should be issued under section 4.

3. Whether EPA commenced "an appropriate proceeding" upon granting the petition is not before the Court, and any challenge to the test orders issued upon granting the petition would be heard in the Circuit Courts of Appeals.

When EPA denies a section 21 petition, it must publish its reasons for the denial. 15 U.S.C. § 2620(b)(3). Section 21 authorizes de novo review of the denial of a petition for a section 4 rule or order. *Id.* § 2620(b)(4(A), (B).

When EPA grants a petition, the agency must “promptly commence an appropriate proceeding in accordance with” the relevant provision of TSCA (in this case, section 4 of TSCA). *Id.* But when the Agency grants a petition for a section 4 rule or order, TSCA section 21 does *not* require that the Agency also explain the exact testing parameters it will propose in the requested section 4 rulemaking proceeding or order. Nevertheless, here, the Agency granted the petition on reconsideration, detailed the section 4 proceedings that it intends to commence (and has already commenced, *see, e.g.*, Notice of TSCA Section 4 Testing Order, ECF No. 65), and explained how those proceedings will address Plaintiffs’ petition. *See* Mem. in Supp. of Mot. to Dismiss 7-10. Because the petition was granted and because TSCA does not provide for review of the grant of a section 21 petition, the inquiry ends and the Court must dismiss the matter for lack of jurisdiction.

But even if Plaintiffs’ petition could somehow be characterized as “denied” and the Court had jurisdiction to hear their claim, whether the intended proceedings that EPA described in its response to Plaintiffs’ petition are “appropriate” is beyond this Court’s scope of review. “Judicial review provisions [] are jurisdictional in nature and must be construed with *strict fidelity* to their terms.” *Stone v. I.N.S.*, 514 U.S. 386, 405 (1995) (emphasis added). The plain language of section 21 limits the Court’s scope of review to one issue—whether it should compel EPA to “*initiate*” a proceeding requested by Plaintiffs under TSCA section 4, 15 U.S.C. § 2620(b)(4) (emphasis added). As EPA explained in its motion to dismiss, the statutory text, legislative history, and case law all confirm that while

the Court can require EPA to initiate proceedings under TSCA, they cannot dictate the results. *See* Mem. in Supp. of Mot. to Dismiss 17-19; *see also id.* at 19-21 (explaining that Plaintiffs’ claim is also moot because section 21 does not authorize the award of any further relief to Plaintiffs).

In any event, Congress did not define the term “appropriate proceeding,” but rather left it to the Agency to determine what proceedings are appropriate in context of each petition. That discretion, of course, is not boundless. Petitions must “set forth the facts” establishing that it is “necessary” to initiate the requested action. 15 U.S.C. § 2620(a), (b)(1). Here, Plaintiffs requested the initiation of a rulemaking proceeding or the issuance of an order under TSCA section 4(a)(1)(A)(i), compelling health and environmental effects testing regarding PFAS. Section 4(a)(1) requires EPA to mandate testing of a chemical substance or mixture upon a finding of certain elements. *Id.* § 2603(a)(1). Thus, Plaintiffs had to show that it is “necessary” to initiate a section 4 proceeding in relation to those mandatory elements set out in section 4. The “appropriate proceeding” in this instance, therefore, is a section 4 proceeding for a rule or order that would fill the information gaps that triggered EPA’s section 4 authority. And final section 4 test orders are subject to judicial review in the courts of appeals pursuant to Section 19 of TSCA. *See* 15 U.S.C. § 2618(a).

For these reasons, as well as those stated in EPA’s motion to dismiss and accompanying briefing, the Court should dismiss this case for lack of jurisdiction.

This 1st day of February 2023.

Respectfully submitted,

/s/ Hubert T. Lee

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2023, I electronically transmitted the foregoing to the Clerk of Court using the ECF system for filing and transmittal of a Notice of Electronic Filing to registered counsel for all parties.

/s/ Hubert T. Lee